
URGENT FIELD SAFETY NOTICE

Date: OCTOBER 7, 2024

Destination: Local vigilance correspondent
Director / Responsible of radiology department

Object: Fiel safety Notice FSN-FSCA_ACAP 24 032_RO

Sir / Madam,

APELEM has become aware of a mechanical problem with a component of its medical device.

Analysis of our database has identified that your facility as having a device to be verified.
We are therefore sending you this safety notice to explain the context and the actions to be taken.

The competent authority of your country has been already informed of this communication.

We apologize for any inconvenience caused. APELEM thanks you for your cooperation in implementing this safety notice. Maintaining the high level of safety and quality remains our top priority.

APELEM Quality department
Vigilance activity



Device description

Remote controlled radiology system

Commercial name	UDI-DI/GTIN	Basic UDI-DI
PLATINUM dRF (8L)	03760172650447	3760172658L8Gsystems5D

Numéro de série			
E248L0111	E248L0114	G248L0149	G248L0150

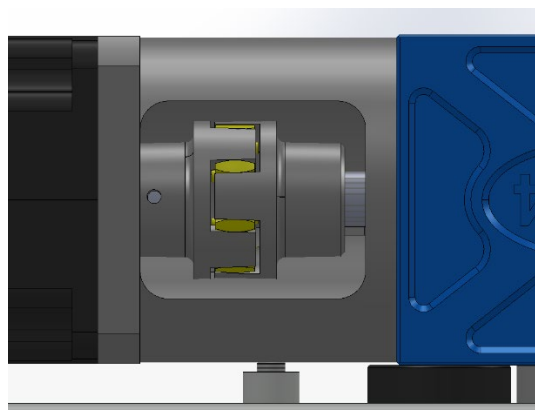
Problem description

An 8L remote-controlled X-ray table is made up of several mechanical components, each providing specific movements such as tilt or lift. The component concerned by this safety alert is an elastomer coupling. This is a system that transmits power and torque from a motor shaft to a rotating receiver shaft, while correcting any mechanical misalignments.

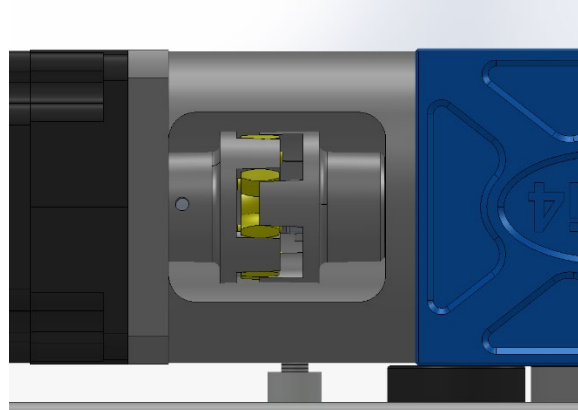
During a maintenance operation to upgrade a component not linked to the mechanical transmission chain, a partial uncoupling of this coupler was detected. In case of total uncoupling, this could lead to a more or less rapid descent of the panel. Two risks are identified depending on the use of the device at time of incident: crushing risk (foot crushing for example) and possible patient fall.

It is important to notify you that no incident has been reported.

Visual of correct coupling positioning



Visual of incorrect coupling positioning



Action to be taken

A verification of each device is done by APELEM with the collaboration of the distributor who installed your device.

If during this verification, the technician detects an uncoupling of the component, he will upgrade the system immediately. Normal use of the device will be resumed as soon as this operation has been completed.

APELEM or its distributor will contact you shortly to organize the verification of your equipment.

In the meantime, devices can be used.

Please acknowledge receipt of this notice and confirm that you have read and understood it by returning the form (page 4) by mail before OCTOBER 25, 2024:

service@dms-imaging.com



RETURN RECEIPT

URGENT FIELD SAFETY NOTICE

Field Safety Corrective Action n° ACAP 24 032_RO

ORGANIZATION

Name

Adress

Contact name

mail / phone

Serial Number of the device in your possession	
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We hereby confirm that we have taken note of this safety alert and distributed it to the personnel and departments concerned.

Complete Name:

Function:

Date:

Sign:

To complete and return before OCTOBER 25, 2024, per mail service@dms-imaging.com

Thanks for your cooperation.

